Learning Health Community

Essential Standards to Enable Learning (ESTEL) Initiative

17-18 April 2014
AHRQ, Rockville, MD
The National LHS: *One Infrastructure* that Supports

- **Research**
  - Clinical
  - Comparative effectiveness
  - Translational

- **Public Health**
  - Surveillance
  - Situational Awareness

- **Quality Improvement**
  - Health process and outcomes research
  - Best practice dissemination

- **Consumer Engagement**
  - Knowledge-driven decision making
What Infrastructure Can Enable

• A **needed** virtuous cycle of study, learning and improvement
• This requires assembly of data, analysis, and feedback
Learning Health System *Core Values*

1. Person-Focused
2. Privacy
3. Inclusiveness
4. Transparency
5. Accessibility
6. Adaptability
7. Governance
8. Cooperative and Participatory Leadership
9. Scientific Integrity
10. Value
54 Endorsements of the LHS Core Values* (As of 5/8/2013)

*To be included on a Learning Health Community public website that will list all organizations that have endorsed the LHS Core Values.
The Learning Health Community

• Grew out of the 2012 “Summit”
• A self-organizing, multi-stakeholder coalition of the willing
• 54 “endorsers” plus ~ 600 others expressing interest
• “Summit” Planning Committee became the Community’s Coordinating Committee
• Catalyzing, leading, and participating in initiatives to realize a Learning Health System
  - Standards (ESTEL)
  - Governance
  - Technology
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
</tr>
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<tbody>
<tr>
<td>12:30 - 1:00</td>
<td>Call to Order, Introductions of Participants</td>
<td>Becky Kush</td>
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<tr>
<td>1:00 - 1:30</td>
<td>Background and Setting the Stage for this LHC ESTEL Meeting</td>
<td>Chuck Friedman, Ken Pool, and Landen Bain</td>
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</table>
| 1:30 – 3:00 | **Current Projects** - *Updates, specifically focusing on the use of standards as enablers in these projects/initiatives and how they fit into the ‘narrow neck’ categories*  
- HHS/ONC – Doug Fridsma  
- ONC Structured Data Capture Initiative – Ken Pool  
- PCORI and Standards – Jeff Brown  
- IOM – Digital Learning Collaborative – Claudia Grossman  
- BRIDG, SHARE, CFAST - Bron Kisler  
- Research Match and keyCRF – Landen Bain  
- FDA Regulatory Guidances and HIT Plans – Ron Fitzmartin  
- TRANSFoRm – Theodoros Arvanitis | Facilitator: Becky Kush |
| 3:00 - 3:30 | Break                                                                                       |                             |
| 3:30 - 5:30 | Preparation for Breakout Groups on Wednesday  
- Definitions/descriptions of the three areas to address at the Narrow Neck of the Hourglass  
- Descriptions of three exemplars of learning cycles: research, public health, quality | Landen Bain, Ken Pool        |
“We seek the development of a learning health system in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation—with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience.”
“Digital health data are the lifeblood of a continuous learning health system... The totality of available health data is a crucial resource that should be considered an invaluable public asset in the pursuit of better care, improved health, and lower health care costs.”

- IOM, 2012
Science: Evidence & Continuous Learning

2014 plans under way & under consideration
- An expert vision paper on the future of clinical research
- Convening CEO & executive leaders on continuous learning
- A case study of a test-bed for real-time digitally-facilitated research
- An expert vision paper on academic medical center leadership for continuous learning

2013 deliverables
- Workshop: Large simple trials for clinical research (Sep report)
- Workshop: Observational studies in CER (Sep report)
- IOM paper: The Common Rule and continuous learning (Aug hearing)
- Workshop: Data harmonization across networks (Oct meeting)
- IOM paper: Return on information systems investments (Jan release)
- Workshop: Improving data quality (Feb dissemination)
- IOM paper: Making the case for clinical data use (Apr release)

Culture: People & Continuous Engagement

2014 plans under way & under consideration
- Formalize national network of patient-family advisory leadership
- Vision and strategy piece on practice models for clinician-patient partnership
- Build the inventory of case studies on clinical data & care improvement
- An expert vision paper and meeting on decision-making tool validation

2013 deliverables
- Workshop/Video: Partnering with Patients (Aug release)
- IOM paper: Team-based care principles and values (Jan dissemination)
- Patient interviews: Patients’ roles as team members (paper in draft)
- Survey: Patient views on clinical data sharing (Jan dissemination)
- Meeting: Patient and family leader partnership (Nov meeting)
The Digital Learning Collaborative (DLC) was created to provide a venue for joint activities that can accelerate progress towards the digital infrastructure necessary for continuous improvement and innovation in health and health care.
IOM Roundtable on Value & Science-Driven Health Care

Digital Learning Collaborative

May 30, 2014
National Academy of Sciences Building
Room 120
2101 Constitution Ave NW
Washington DC

Meeting goals

1. Together with the Learning Healthcare Community’s Essential Standards to Enable Learning (ESTEL) working group, convene essential stakeholders, including standards groups, federal agencies, academic health systems (AHSs), and electronic health record (EHR) and research technology vendors around the issue of the implementing standards-based EHR-enabled research.

2. Describe approaches to EHR-enabled research, including those based on the ONC Structured Data Capture (SDC) Initiative, CDISC Healthcare Link, IHE Quality, Research and Public Health, and FDA eSource Guidance and identify how to realize available opportunities.

3. Identify opportunities for vendors, interested AHSs, and research sponsors to accelerate progress towards more widely implemented EHR-enable research.
BRIDG, SHARE, CFAST

Bron Kisler, VP, Strategic Alliances, CDISC
• Single, trusted, authoritative source for CDISC data standards
• Concepts, metadata, collections, relationships, value sets across the full spectrum of CDISC content
• Aligned with NCI Semantic Systems
• Links research to healthcare concepts to support interoperability

Adapted from Source by Sue Dubman, Sanofi-Aventis
SHARE MDR Framework

A Versioned Standard is comprised of a set of Operational Collections and associated variables and rules for a specific use case (e.g., SDTM, CDASH).

An Operational Collection is a grouping of Research Concepts. There may be additional rules between objects within the Operational Collection. An Operational Collection may be analogous with a SDTM Domain, a CRF, an ADaM data set, or a similar level of operational structure.

Basic elements that are the foundation for the content described in the SHARE repository. A Research Concept defines one or more related pieces of clinical data, which is developed using an Integrated BRIDG / ISO 21090 Template.

Integrated BRIDG / ISO 21090 Templates use BRIDG classes and relationships to fashion small re-usable patterns that are commonly needed in clinical research.

BRIDG is the foundation model for SHARE that provides classes, attributes and associations use to creates core building blocks.

Source: Sam Hume, VP SHARE Development
Therapeutic Area Standards Governance

CFAST SAC
Scientific Advisory Committee
- Provides Scientific Advice to TAPSC
- Identifies Risks and Opportunities
- Identifies/Engages Relevant Partners

CFAST TAPSC
Therapeutic Area Program Steering Committee
- Prioritizes/Approves Proposals
- Approves Projects & Charters
- Resources & Oversees Projects

CDISC TA Standards Project Teams
Project Leader +
Clinical leads (SMEs), BRIDG Modeler, Concept Creators, Terminologists, Metadata Analysts, Stats Consultants, Writers, Communications

Ongoing Maintenance & Enhancement of Foundational CDISC Standards

Research Community
Data Standards in
Regulated Clinical Research and
FDA Review

Ron Fitzmartin, PhD, MBA
Sr. Advisor
Data Standards Program
Office of Strategic Programs
Center for Drug Evaluation and Research
Food and Drug Administration

ESTEL Meeting
Rockville, MD
April 17, 2014
Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the Food and Drug Administration.
Regulated Clinical Research

Clinical Site

Possibly disparate systems for:
- Pt Visit Records
- Pharmacy Labs
- Labs, etc.

Sponsor / CRO

EDC

SAE

FDA

SDTM
ADaM
SEND

Data Standards

Protocol Data Capture Exchange Analysis CSR Submission
Data Standards @ the Foundation of Regulatory Review
Guidance & Binding Guidance to Industry

Guidance for Industry
Electronic Source Data in Clinical Investigations

Guidance for Industry
Providing Regulatory Submissions in Electronic Format — Standardized Study Data

DRAFT GUIDANCE
This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this draft document contact (CDER) Ron Furmanto at 301-796-5333, (CBER) Office of Communication, Outreach and Development (OCOD) at 301-827-1800 or 1-800-835-4709.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

September 2013
Procedural

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Food and Drug Administration
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February 2014
Electronic Submissions
Revision 1